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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,981	12/16/2005	Thomas Kaup	8932-988-999	5254
51832	7590	01/22/2008		
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 01/22/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,981

Applicant(s)

KAUP ET AL.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17, 19, 20 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17, 19, 20 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This action is in response to applicant's amendment received on 10/23/2007.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described, as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 10-13, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of Hardinge (U.S. Patent 2,381,050).

Regarding claims 1, 3, and 23, Lawes discloses a device comprising an intramedullary pin and a bone fixation implant. The intramedullary pin includes a longitudinal axis and at least one transverse borehole defining a central borehole axis, wherein the central borehole axis forms a non-zero angle with respect to the longitudinal axis of the pin. The bone fixation implant includes a front end, a rear end, and a shaft. Lawes fails to disclose the bone fixation element including a first elastically expandable sheath at the front end of the bone fixation implant and an expansion element. Hardinge teaches various embodiments, for example Figures 5 and 6, of a device comprising a bone fixation implant that includes an elastically expandable sheath and an expansion agent in order to forcibly draw together adjacent bone fragments (column 1 lines 45-50) and to radially expand the split ends of the sheath (column 3 lines 15-27; see Figure 1

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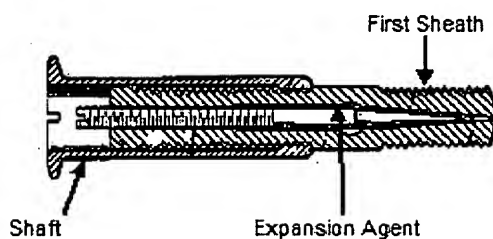
below). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Lawes with a bone fixation implant further including an elastically expandable sheath and an expansion agent in view of Hardinge in order to forcibly draw together adjacent bone fragments and to radially expand the split ends of the sheath.

Further regarding claims 1, 3 and 23, the combination of Lawes and Hardinge disclose a device wherein the expansion agent includes a threaded outer surface and the first expandable sheath includes an inner threaded surface that engages the outer threaded surface, wherein the expansion agent is capable of moving along the central borehole axis to expand the sheath. Regarding claim 2, the combination of Lawes and Hardinge disclose a device wherein optional expansion of the first expandable sheath changes the cross-sectional shape of at least a portion of the bone fixation implant to impede rotation of the implant relative to the bone. Regarding claim 10, the combination of Lawes and Hardinge disclose a device wherein the shaft and the sheath of the bone fixation element are axially joined to one another prior to insertion through the transverse borehole. Regarding claim 11, the combination of Lawes and Hardinge disclose a device further comprising a safeguard capable of preventing rotation of the bone fixation implant relative to the intramedullary pin about the central borehole axis. Regarding claim 12, the combination of Lawes and Hardinge disclose a device further comprising an external thread on the first sheath. Regarding claim 13, the combination of Lawes and Hardinge disclose a device wherein the first elastically expandable sheath of the bone fixation implant is configured as a blade. The examiner believes that the

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separate element of the first expandable sleeve can be interpreted as a plurality of blades extending radially outward. Regarding claim 19, the combination of Lawes and Hardinge it is noted that the combination of Lawes and Hardinge appear to be substantially identical to the device claimed, although produced by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983). Regarding claim 20, the combination of Lawes and Hardinge disclose a device wherein the expansion agent is operably connected with the shaft by a threaded connection. There is no requirement in the claims that the expansion agent and the shaft are directly connected by a threaded connection. Furthermore, the examiner is unable to find a written description or Figures of an embodiment wherein the expansion agent is directly connected to the shaft.

Figure 1



4. Claims 3-9, 14, 15, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of Hardinge (U.S. Patent 2,381,050) further in view of Shannon (U.S. Publication 2005/0113909).

Regarding claims 3-9, 14, and 23-26, the combination of Lawes and Hardinge disclose the invention as claimed except for the bone fixation implant further comprising

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a second expandable sheath disposed on the first expandable sheath. Shannon teaches gluing polymer coatings to the external surface of expandable implants in order to make the implants more biocompatible (page 3 paragraph 025). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Lawes modified by Hardinge with a bone fixation implant further including a polymer coating glued to the first expandable sheath in view of Shannon in order to make the implant more biocompatible.

Further regarding claims 6-8, it is noted that the combination of Lawes, Hardinge, and Shannon appear to be substantially identical to the device claimed, although produced by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983). Further regarding claim 14, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the second expandable sheath is disposed on the first expandable sheath coaxial with the central borehole axis. Regarding claims 15, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the second expandable sheath is constructed as a blade. The examiner believes that if the first expandable sleeve can be interpreted as a plurality of blades extending radially outward then a second sheath glued onto the first sheath would also be in the form of a blade. Further regarding claim 23, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the expandable sheaths are capable of optional expansion in at least one direction transverse to the central longitudinal axis after the bone fixation implant has been inserted into bone. Regarding claim 24, the

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combination of Lawes, Hardinge, and Shannon disclose a device wherein the optional expansion of the expandable sheaths changes the cross-section shape of at least a portion of the bone fixation implant to impede rotation of the implant relative to the bone. Regarding claim 25, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the shaft and the expandable sheaths are axially joined to one another prior to insertion through the transverse borehole. Regarding claim 26, the combination of Lawes, Hardinge, and Shannon disclose a device wherein the first expandable sheath includes an outer thread.

5. Claims 17 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of Hardinge (U.S. Patent 2,381,050) further in view of Shannon (U.S. Publication 2005/0113909) further in view of Herb (U.S. Patent 4,636,123).

Regarding claims 17 and 27, the combination of Lawes, Hardinge, and Shannon disclose the invention as claimed except for the expansion agent including a tapered cone tapered toward the rear end of the device. The combination of Lawes, Hardinge, and Shannon disclose a device comprising an expansion agent including a tapered cone tapered toward the forward end of the device in order to expand a sheath. Herb teaches a device comprising an expansion agent including a tapered cone tapered toward the rear end of the device in order to expand a sheath. Because both the combination of Lawes, Hardinge, and Shannon and Herb teach devices comprising an expansion agent including a tapered cone for expanding a sheath, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

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substitute one expansion agent for the other in order to achieve the predictable result of expanding a sheath.

Response to Arguments

6. Applicant's arguments with respect to claims 1-14, 17, 19, 20, and 23-27 have been considered but are moot in view of the new ground(s) of rejection. The examiner has presented new grounds of rejection as discussed above. The new grounds of rejection were necessitated by amendment making this office action **FINAL**.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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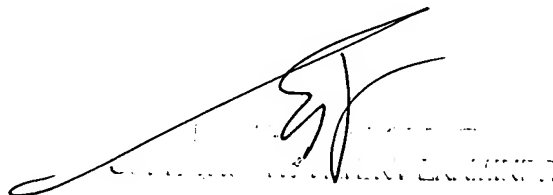
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWWW



NICHOLAS WOODALL
Examiner